

### **REMARKS**

Claims 1, 5-14, 17-39 and 44-56 are pending in the application. Claim 48 is amended.

The telephonic interview between Joyce C. Hersh, Applicant's representative, and the Examiner held on June 7, 2005, is acknowledged with appreciation, wherein the outstanding issues of the March 15, 2005 Office Action were discussed.

#### **Claim Rejection Under 35 U.S.C. § 112, Second Paragraph**

Claim 48 was rejected as indefinite. During the telephonic interview, it was explained that this claim included an inadvertent typographical error. Specifically, claim 48 pertains to a tandem repeat of the replicon, and so should have recited nucleotides 2955-4960, rather than 2955-2960. This is corrected herein. Applicant has also taken the Examiner's suggestion that the phrases "nucleic acid molecule" and "nucleic acid" be replaced with "polynucleotide".

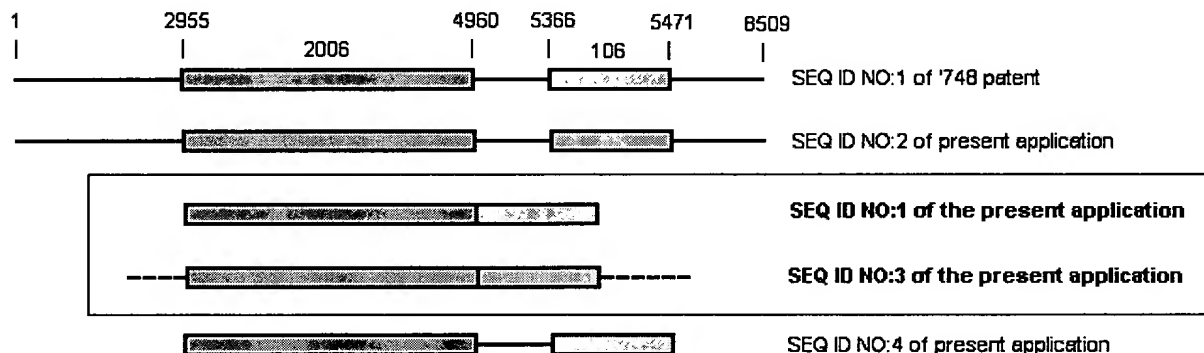
Reconsideration and withdrawal of this rejection is respectfully requested.

#### **Double Patenting**

The claims were rejected under the judicially-created doctrine of obviousness-type double patenting as unpatentable over the claims of U.S. Pat. No. 6,503,748 ("the '748 patent"). A Terminal Disclaimer is filed herewith.

This issue was discussed during the telephonic interview. During the interview, the differences between the sequence of the '748 patent and the sequences of the present application were also discussed, and Applicant's representative explained that the claims of the present application are patentably distinct, novel and not obvious in

The claims of the '748 patent all reference a single sequence, SEQ ID NO:1. No other sequences are presented in that patent specification. In contrast, the present application discloses four sequences, of which SEQ ID NO:2 is identical to the sequence of the '748 patent. The relationships of these four sequences to the sequence disclosed in the '748 patent are shown in the diagram below.



SEQ ID NO:1 and SEQ ID NO:3 of the present application are set off in the box above, and are novel and not obvious in view of the '748 patent. As can be seen from this illustration, SEQ ID NO:1 of the present application consists of two spliced-together portions of sequence from the '748 patent: the first portion (dark grey bar) is 2006 nucleotides in length (nucleotides 2955 through 4960 of the sequence from the '748 patent), and the second portion (light grey bar) is 106 nucleotides (nucleotides 5366 through 5471 of the sequence from the '748 patent). This was also shown in the sequence alignment filed as Exhibit B with the Request for Continued Examination

(RCE) of December 29, 2004.<sup>1</sup> SEQ ID NO:3 contains the same nucleotide sequence as SEQ ID NO:1 (dark and light grey bars), and also additional leading and trailing portions (dashed lines) of sequence not found in either SEQ ID NO:1 or the sequence disclosed in the '748 patent. These leading and trailing portions are required for the shuttle vector activity of SEQ ID NO:3.

Viewed another way, SEQ ID NO:1 and SEQ ID NO:3 of the present application are conceptually analogous to "deletion mutants" of the sequence of the '748 patent. The '748 patent does not disclose or suggest that nucleotides 4961 through 5365 can or should be deleted. SEQ ID NO:1 and SEQ ID NO:3 are therefore novel and nonobvious in light of the '748 patent.

Independent claims currently pending in the application are claims 1, 27, 28, 48, 49 and 52. These claims (and their respective dependent claims) are patentably distinct from the claims of the '748 patent because the claims of the present application all rely on SEQ ID NO:1 and SEQ ID NO:3 as shown above, both of which are novel and not obvious in light of the sequence disclosed in the '748 patent.

Claim 1 recites "[a]n isolated or purified nucleic acid molecule comprising a *Ketogulonigenium* plasmid replicon **as shown in SEQ ID NO: 1.**" Claim 1 therefore requires SEQ ID NO:1 as it is shown in the diagram above, which is a sequence that is not disclosed or suggested in the '748 patent. Claim 1 (and dependent claims 5-14, 17-26, 31-39, 44-47 and 53-54) is therefore patentably distinct from the claims of the '748 patent.

Independent claim 27 recites a method for producing a polypeptide, where the method includes culturing a host cell that contains a polynucleotide containing a

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<sup>1</sup> It should be noted that there is a slight discrepancy in the alignment of Exhibit B and the above diagram. In the alignment, the BLAST results show a 2-nucleotide overlap between the two sections. That is, in seeking to align SEQ ID NO:1 of the present application with the sequence from the '748 patent, the BLAST program used nucleotides 1 through 2006 of SEQ ID NO:1, and then 2005 through 2112. Nucleotides 2005 and 2006 were therefore "used twice." The diagram above uses nucleotides 2005 and 2006 only once, and so the regions are listed as 2955-4960 and 5366-5471.

*Ketogulonigenium* plasmid replicon as shown in SEQ ID NO:1. Independent claim 28 recites a method of transforming a host cell, and this method also relies on the plasmid replicon "as shown in SEQ ID NO:1". Like claim 1, these claims (and dependent claims 29-30) are patentably distinct from the claims of the '748 patent.

Independent claim 48 recites a polynucleotide containing a *Ketogulonigenium* plasmid replicon, where the sequence is at least 95% identical to nucleotides 2955-4960 of SEQ ID NO:2, immediately followed by another sequence at least 95% identical to nucleotides 2955-4960 of SEQ ID NO:2. SEQ ID NO:2 of the present application is identical to the sequence disclosed in the '748 patent. However, there is no teaching or suggestion in the '748 patent that portions of the sequence should be arranged in this way. This claim, and dependent claim 55, are therefore patentably distinct from the claims of the '748 patent.

Independent claims 49 and 52 both rely on SEQ ID NO:3. Claim 49 discloses a shuttle vector that has at least 95% sequence identity to SEQ ID NO:3. Like SEQ ID NO:1, SEQ ID NO:3 contains two separate portions of the sequence of the '748 patent, one immediately following the other. SEQ ID NO:3 additionally has leading and trailing portions of sequence not found in SEQ ID NO:1. These leading and trailing portions are different from the sequence of the '748 patent. Claims 49 and 52 (and dependent claims 50-51 and 56) are therefore patentably distinct from the claims of the '748 patent.

Applicant's representative wishes to correct an inadvertent misstatement made during the telephonic interview. During the interview, Applicant's representative stated that the leading and trailing sequences in SEQ ID NO:3 (*i.e.*, those sequences before and after the replicon) were identical to the sequences before and after the equivalent regions in the sequence of the '748 patent. However, a review of the Exhibit C filed with the RCE of December 29, 2004 shows that these leading and trailing sequences have **no** identity with the sequence of the '748 patent. These are therefore represented by dashed lines in the diagram above. Applicant's undersigned representative apologizes for the mistake.

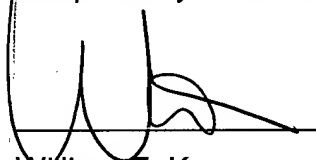
As discussed above, Applicant respectfully submits that the claims are presented herein are patentably distinct over the claims of the '748 patent. Accordingly, reconsideration and allowance of all claims pending in the present application are respectfully requested.

If the undersigned can be of assistance to the Examiner in addressing issues to advance the application to allowance, please contact the undersigned at the number set forth below.

15 June 2005

Date

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'W. E. Kuss', written over a horizontal line.

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